Melissa E. Flax (mflax@carellabyrne.com)
Michael Cross (mcross@carellabyrne.com)
CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700 (Phone)
(973) 994-1744 (Facsimile)

Of counsel:
Claire Laporte (claporte@foleyhoag.com)
Sarah Cooleybeck (scooleybeck@foleyhoag.com)
Sarah S. Burg (sburg@foleyhoag.com)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000 (Phone)
(617) 832-7000 (Facsimile)

Attorneys for Plaintiff, Fresenius Medical Care Holdings, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRESENIUS MEDICAL CARE HOLDINGS, INC. Plaintiff, v. NOVEL LABORATORIES, INC. Defendant.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Fresenius Medical Care Holdings, Inc. ("FMCHI") for its Complaint against Novel Laboratories, Inc. ("Novel") alleges as follows:

THE PARTIES

1. FMCHI is a New York corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

2. Upon information and belief, Novel is a Delaware company having its principal place of business at 390 Campus Drive, Somerset, New Jersey 08873

NATURE OF ACTION

3. This is a civil action for declaratory and injunctive relief against Novel for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Novel's submission of ANDA No. 207525 to the Food and Drug Administration ("FDA") for approval to market a generic copy of FMCHI's PhosLo® GelCaps calcium acetate drug product.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.§§ 1331, 1338(a), 2201 and 2202. Specifically, on information and belief, Novel included in ANDA No. 207525 a certification under Paragraph IV of Section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"), with respect to United States Patent No. 6,576,665 (the "'665 patent"), a patent assigned to FMCHI. Under the Hatch-Waxman Act, the filing of a so-called "Paragraph IV certification" with respect to a patent constitutes an act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Accordingly, this case presents a question of federal law over which the Court has exclusive subject matter jurisdiction.

5. This Court has personal jurisdiction over Novel at least by virtue of the fact that Novel conducts business in the New Jersey, has availed itself of the rights and benefits of New Jersey law, and/or has engaged in substantial and continuing contacts with the New Jersey. In

addition, this Court has personal jurisdiction over Novel because it has a principal place of business in New Jersey.

6. Novel, individually and/or jointly with its affiliate Gavis Pharmaceuticals, is in the business of making and selling drug products in the United States.

7. Venue is proper in this jurisdiction under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I: INFRINGEMENT OF THE '665 PATENT

8. FMCHI is the assignee of the '665 patent and holder of New Drug Application ("NDA") No. 21-160, upon which Novel's ANDA No. 207525 is based. A copy of the '665 patent is attached as Exhibit A. The claims of the '665 patent are valid and enforceable.

9. Novel's submission of the ANDA No. 207525 constitutes infringement of the '665 patent. On information and belief, Novel included within its ANDA a Paragraph IV certification to the effect that the '665 patent is invalid, unenforceable, and/or would not be infringed by its proposed generic copy of FMCHI's PhosLo® GelCaps calcium acetate drug product. The submission of this certification constitutes an act of infringement of one or more claims of the '665 patent because the proposed generic drug is covered by one or more claims of the '665 patent, and/or because its use is covered by the '665 patent. *See* 35 U.S.C. § 271(e)(2)(A).

10. By its letter dated January 6, 2015 ("Notice Letter"), Novel notified FMCHI of its ANDA filing seeking approval to engage in the commercial manufacture, use, and sale of generic calcium acetate product before the expiration dates of the '665 patent.

11. In the Notice Letter, Novel notified FMCHI that its ANDA contained a Paragraph IV certification alleging that in its opinion no valid claim of the '665 patent would be infringed by its proposed generic calcium acetate drug product.

12. Upon information and belief, Novel intends to, and will, engage in the commercial manufacture, use, and sale of its generic calcium acetate drug product promptly upon receiving FDA approval to do so.

13. Upon FDA approval of Novel's ANDA No. 207525, Novel will infringe one or more claims of the '665 patent by making, offering to sell, importing, or selling its proposed generic calcium acetate drug product in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

14. FMCHI has the right and standing to enforce the '665 patent and bring this action.

15. Novel had notice of the '665 patent at the time of its infringement. Novel's infringement has been, and continues to be, willful and deliberate.

16. FMCHI will be substantially and irreparably damaged and harmed if Novel's infringement is not enjoined. FMCHI does not have an adequate remedy at law.

17. This Complaint is being filed before the expiration of the forty-five days from the date FMCHI received the Notice Letter.

COUNT II: INFRINGEMENT OF THE '445 PATENT

18. Upon information and belief, Novel intends to, and will, engage in the commercial manufacture, use and sale of its generic calcium acetate drug product promptly upon receiving FDA approval to do so.

19. Such commercial manufacture, use and sale of Novel's generic calcium acetate drug product will constitute infringement under 35 U.S.C. § 271 of United States Patent No. 6,875,445 (the "'445 patent"), assigned to FMCHI, which has the right and standing to enforce the '445 patent. A copy of the '445 patent is attached as Exhibit B.

20. There is a justiciable controversy between the parties hereto as to infringement of the '445 patent. Novel's submission of ANDA No. 207525 to the FDA constitutes activity

directed toward infringing and a refusal to change course in the face of acts sufficient to create reasonable apprehension of forthcoming suit. Accordingly, there is a sufficient case or controversy under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

21. FMCHI will be substantially and irreparably damaged and harmed if Novel's infringement is not enjoined. FMCHI does not have an adequate remedy at law.

PRAYER FOR RELIEF

Accordingly, FMCHI respectfully requests the following relief:

a. A judgment declaring that Novel has infringed the '665 patent and the '445 patent, and that Novel's making, using, selling, offering to sell, or importing of its generic calcium acetate drug product will infringe the '665 patent and the '445 patent;

b. A judgment providing that the effective date of any FDA approval for Novel to make, use or sell its generic calcium acetate drug product be no earlier than the date on which the '665 patent and the '445 patent expire;

c. A judgment permanently enjoining Novel from making, using, selling, offering to sell, or importing its generic calcium acetate drug product until after the expiration of the '665 patent and the '445 patent;

d. If Novel engages in the commercial manufacture, use, offer to sell, or sale of its generic calcium acetate drug product prior to the expiration of the '665 patent and the '445 patent, a judgment awarding FMCHI damages or other monetary relief, increased to treble the amount found or assessed, together with interest;

e. Attorney's fees pursuant to 35 U.S.C. § 285;

f. Costs and expenses in this action; and

g. Such further and other relief as the Court may deem just and proper.

Dated: February 20, 2015

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO

By: */s/ Melissa E. Flax*

Melissa E. Flax (mflax@carellabyrne.com)
Michael Cross (mcross@carellabyrne.com)
5 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700 (Phone)
(973) 994-1744 (Facsimile)

Of counsel:
Claire Laporte (claporte@foleyhoag.com)
Sarah Cooleybeck (scooleybeck@foleyhoag.com)
Sarah S. Burg (sburg@foleyhoag.com)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000 (Phone)
(617) 832-7000 (Facsimile)

Attorneys for Plaintiff,
Fresenius Medical Care Holdings, Inc.